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EXAMINER	
WESSENDORF, TERESA D	

ART UNIT	PAPER NUMBER
1639	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/849,781	SNYDER ET AL.	
	Examiner	Art Unit	
	TERESA WESSENDORF	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11, 141, 164, 169, 173, 174, 177, 181-186, 188 and 193-195* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/20/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1-16,93-101,106,107,112-133,138-159,162,164,165,167,169,171,173-175,177,181-186,188 and 193-197.
Continuation of Disposition of Claims: Claims withdrawn from consideration are 12-16,93-101,106,107,112-133,138-140,142-159,162,165,167,171,175,196 and 197.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/2/09 has been entered.

Claims Status

Claims 1-16, 93-101, 106, 107, 112-133, 138-159, 162, 164-165, 167, 169, 171, 173-175, 177, 181-186, 188, and 193-197 are pending.

Claims 17-92, 102-105, 108-111, 134-137, 160-161, 163, 166, 168, 170, 172, 176, 178-180, 187, 189-192 and 198 have been cancelled.

Claims 12-16, 93-101, 106, 107, 112-133, 138-140, 142-159, 162, 165, 167, 171, 175 and 196-197 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected species, there being no allowable generic or linking claim.

Claims 1-11, 141, 164, 169, 173, 174, 177, 181-186, 188 and 193-195 are under consideration in this Office Action.

The inadvertent indication that claims 173-174, 177, 181-186, 188 and 192-195 are withdrawn from consideration at page 2 of the last Office action is regretted. These claims have been rejected throughout the Office action, as stated by applicants and the rejections are reiterated as shown below. Applicants' request that these claims be confirmed as not withdrawn from examination in the instant application is hereby granted.

Withdrawn Objection and Rejections

In view of applicants' arguments and amendments to the claims, the 35 USC 112, first paragraph (new matter); second paragraph and obviousness double patenting rejections have been withdrawn.

Claim Rejections - 35 USC § 112

Claims 1-11, 141, 164, 169, 173, 174, 177, 181-186, 188 and 193-195, as amended, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A "written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula [or] chemical name of the claimed subject matter sufficient to distinguish it from other materials". University of California v. Eli Lilly and Col, 43 USPQ 2d 1398, 1405(1997), quoting Fiefs V. Revel, 25 USPQ 2d 1601m 16106 (Fed. Cir. 1993.

The claimed invention is drawn to a positionally addressable array comprising a plurality of different substances on a solid support, with each different substance being at a different position on the solid support, wherein the density of the different substances on the solid support is at least 100 different substances per cm2, and wherein the plurality of different substances comprises 61 purified active kinases or functional kinase domains thereof of a mammal, 61 purified active kinases or functional kinase domains thereof of a yeast, or 61 purified active kinases or functional kinase domains thereof of a Drosophila.

The specification fails to provide an adequate written description of 61 purified kinase and functional domains thereof from any organism such as mammals, bacteria, viruses. The specification provides general statements of these various

kinases in an organism which are not a detail description of the invention. The detail description in the specification (Example I, page 27) describes the 122 kinase genes specifically from the yeast genome, not from the broad claimed any kinase from any type of organisms or functional domains thereof. A written description of a single species would not be a written description for the genus as claimed. At the time of applicants' invention kinases in any organism included in the huge scope of the claim has not been fully characterized such that it has been positioned in an array without denaturing the purified protein. A skilled artisan recognizes that one cannot rule out the possibility that kinases other than the desired enzyme can contaminate any type of purification preparations. Notwithstanding this, the kind/type and preparation of a substrate compatible with the purified protein is also a factor to consider for a purified protein to be active in an array. Furthermore, "although most of the kinases were active in [our] assays, several were not. Presumably, our preparations of these latter kinases either lack sufficient quantities of an activator or were not purified under activating conditions. For example, Cdc28 which was not active in our assays, might be lacking its activating cyclins. For the case of Hog1, cells were treated

with high salt to activate the enzyme….” (paragraph [0161] of the instant specification, publication no. 20030207467).

Attention is also drawn to the numerous prior art cited by applicants, inter alia, the Anderson reference, which teaches the numerous unforeseeable factors of a purified kinase positioned in an array.

Anderson states that:

> …protein microarrays have still not found widespread use, in part because producing them is challenging. Historically, it has required the high-throughput production and purification of protein, which then must be spotted on the arrays. Once printed, concerns remain about the shelf life of proteins on the arrays.

Shaw et al (Drug Discovery and Development, Exhibit B) concords with the statement that:

> "[i]t was first thought that protein biochips would just be an extension of DNA microarrays, and that hasn't exactly panned out," says Bodovitz. That's because proteins have proven to be much trickier to work with in array format than their genomic counterparts. First of all, there are issues of stability. Membrane proteins, for example, make up the majority of potential drug targets, but they're particularly challenging to stabilize. Then there's the choice of immobilization technique, which determines how well the target protein presents itself to the capture agent, and the problem of nonspecific binding. And of course, proteins are inherently unstable outside their natural habitat of living cells, making them much more challenging than DNA to tag and manipulate.

An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations

using such descriptive means as words, structures and formulas to show that the invention is complete. Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQM 1961, 1966 (Fed. Cir. 1997); MPEP 2163. Herein, kinase has been described only in words. The characterization of the different kinases from one organism to another from the numerous kinases and numerous organisms has not been adequately described to distinguish one from the other. To date only a few organisms are fully characterized and the kinase region has not been fingerprinted in a partly or even fully characterized gene. The description lacks structural characterization of a purified kinase as generically claim. It does not distinguish one kinase from another and/or one organism from another positioned in any kind/type of substrate array and reasonably expect the purified kinase to retain its active form.

Claim Rejections - 35 USC § 112

Claims 1-11, 141, 164, 169, 173, 174, 177, 181-186, 188 and 193-195, as amended, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for yeast protein' kinases of the Ser/Thr and tyrosine kinase family, does not reasonably provide enablement for the broad scope of an array of 61 kinases and functional domain kinase

from an organism as mammal, yeast or Drosophila. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for reasons as repeated below.

The claimed array comprises a broad genus of compositions. The claimed different substances encompass any members of the protein kinase from the organism of 'mammal, yeast, or Drosophila' which is broader than the enabling disclosure. The claimed array represents enormous scope because the claims do not place any limitations on the kind, number and/or length of kinase either singly from one family of organism or a combination(s) from the different numerous recited organisms. The instant specification is directed to an array comprising a plurality of different yeast protein kinase, specifically 122 different yeast protein' kinases of the Ser/Thr and tyrosine kinase family members (see specification: example I, pg. 27, line 19 thru pg. 35, line 20; example II, pg. 41, line 19 thru pg. 43, line 6). The specification does not provide reasonable assurance to one skilled in the art that the 61 kinases found in the yeast could be found in any or all of the organisms such as mammals especially the functional domain thereof. It is not apparent from the specification whether the same number of

kinases or the kind of kinases or functional domain thereof can be found in any other organisms and made into an array. It is not apparent from the disclosure as to the functional domain of the kinase and the specific function attributed to said kinase positioned on the array. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. In a highly unpredictable art, as biotechnology, where one cannot predict whether one species would be predictive to the huge scope of the claim, one cannot make a priori statement without any experimental studies. Factors such as the compatibility of the array with the substrate and compounds disposed therein, the compounds (kinases) itself and other unpredictable variables can affect the active form of any kinase. Thus, one cannot predict from a single species its correspondence or extrapolation to the genus, as claimed.

Response to Arguments

Applicants note that the use of kinases from other organisms, including mammals and Drosophila, in the arrays of the presently claimed invention would not have required undue experimentation, but rather, simple, straightforward experiments. The protein kinases and functional kinase domains for use in the presently claimed invention are all well-known,

well-characterized proteins that the ordinarily skilled artisan would easily comprehend.

In reply, attention is drawn to the instant disclosure at e.g., Example I which states that the tyrosine kinase family members do not exist although seven protein kinases that phophorylate have been reported. Applicants' arguments that array from any organisms are simple and straightforward are inconceivable given only the single species in the specification.

Applicants rely on the Hanks reference for its disclosure that "there are now hundreds of different members [of the kinase superfamily] whose sequences are known." Hanks and Hunter, page 576. Furthermore, kinases, for example serine kinases, were already readily recognized in 1995 by virtue of their conserved subdomains. Applicants similarly rely on numerous references and the Synder declaration to show that kinases are well-characterized and known in the art.

In reply, there is nothing in Hanks' reference that discloses these hundreds of kinases are from any mammals or Drosophila or from any other origin as broadly claimed.

All of the references cited by applicants and the Synder declaration provide also only general statements. The characterization is for a specific kinase not in purified and

active form that has been positioned in an array for any kind of organisms fully or partly characterized. Each of the references and the declaration fail to take in consideration the numerous factors of the claim genus array besides the characterization of the kinase. For example, none of the references describes how the numerous kinases from different mammals, different strains of yeast or Drosophila can be purified. How this pure kinase has been positioned in an array and still remains active. Applicants' statements throughout the REMAKRS as to the skepticism in the art provide evidence as to the high unpredictability in the art. Furthermore, applicants in the specification (Published patent 20030207467) states at e.g., paragraph [0038] FIG. 1b, that from three attempts, 106 kinase proteins were purified. **In spite of repeated attempts**, the last 14 of 119 GST fusions were undetectable by immunoblotting analysis. Further, at page 34 of the instant REMARKS, applicants state:

> In Ge, "UPA, a universal protein array system for quantitative detection of protein-protein, protein-DNA, protein-RNA and protein-ligand interactions the author was only able to produce arrays comprising 48 proteins at a very low density, utilizing a traditional purification format. Extension of this disclosure to arrays comprising at least 100 different substances per cm2 would have required **extensive, undue experimentation** beyond the scope of the disclosure provided in this reference. (Emphasis added.)

Thus, an enabling disclosure for a single species of a protein would not be enabling for the broad scope of other protein kinases from any kind of organisms. [Reciting the kinase is a Thr/Ser and Tyr of a yeast protein would overcome this rejection.)

Claim Rejections - 35 USC § 112

Claims 1-11, 141, 164, 169, 173, 174, 177, 181-186, 188 and 193-195, as amended, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claim 1, the metes and bounds of the claim "functional kinase domains" is vague and indefinite as to the kind, length or region the domain encompasses in a purified, active form to be a functional kinase. It is not clear whether the functional kinase domain is positioned together with the full length kinase with the 61 different kinases from the different organisms. And, still expect to be pure and active without being masked by the full length kinases.

B. Non-sequitur for "the solid support" in claims 11 and 141. The base claim 1 does not recite a solid support. Also,

"the organism" in claim 164, claim 169, claim 173, 175 and 177: "the serine/threonine kinase family", "the tyrosine kinase family" in claims 194 and 195 all lack antecedent basis of support from the base claim 1.

C. Claim 174 depends on canceled claim 166.

D. Claims 181-186 and 193 which each recite an organism broaden the base claim 1. Claim 1 recites mammals, yeast and Drosophila. However, organisms include e.g., bacteria, viruses and other organisms besides the ones recited therein. Furthermore, claim 1 recites 61 different kinases however, claims 182-186 recites 92, 110, 116, 119 and 122 recite purified active kinases which is broader than the 61 purified kinase recited in claim 1.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102/§ 103

Claims 1-11, 141, 181-186, 188, and 193-195, as amended, are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Uetz et al (Nature, 2/10/2000) for reasons of record as reiterated below.

Uetz et al, throughout the reference, teach a protein array representing yeast genome encoded proteins (see Abstract of

the reference). The reference teaches fusing roughly 6000 potential ORFs (genes) from yeast genome (which comprises approximately 6000 genes) (see page 623, left col., 1st paragraph. and page 624, left col., 2nd paragraph). Uetz teaches the yeast proteins were expressed in 96-well assay plates (page 624, left col., bottom of 2nd paragraph), which reads on a solid support of the addressable array of claim 1 because each well of the plates would have defined (or addressable positions). The reference also teach each of the protein encoded by a gene is expressed individually in individual wells of the plates as shown in Figure 1 of the reference (page 624), which reads on each protein being at a different position on a solid support of claim 1, for example. The claimed kinase present in the array would have been inherent to the yeast array taught by Uetz since yeast inherently contain kinase in its structure or would have been obvious to determine given the identified genome of yeast as taught by Uetz.

> Where the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See In re Ludtke, supra. Whether the rejection is based on "inherency" under 35 USC 102, on "prima facie obviousness" under 35 USC 103, jointly or

alternatively, the burden of proof is the same as is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. See In re Brown, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972); In re Best 195 USPQ 430 (CCPA 1977).

Response to Arguments

Applicants submit that Uetz does not disclose the preparation of an array comprising purified active kinases, and hence, cannot anticipate the presently claimed invention. As set forth in the Methods section of Uetz, at page 627, the disclosed arrays were prepared by transferring patches of transformed yeast cells into wells of a micro-array assay plate. Uetz does not disclose any purification of the yeast proteins prior to placement in the assay plate, just simply transfer of the transformed cells. Hence, Uetz does not disclose the use of purified kinases or functional kinase domains, as recited in present claim 1. Applicants acknowledge that, even assuming the arrays disclosed in Uetz comprise 61 kinases, there is no disclosure in Uetz sufficient to render obvious the construction of an array of at least 61 kinases or functional kinase domains, in which the array comprises kinases that are purified and active, as recited in present claim 1.

In response, applicants' arguments as to the construction of the array are not commensurate in scope with the claims. The claims are drawn to an array and not to a method of making the

array. Nonetheless, attention is drawn to the disclosure of Uetz at e.g., paragraph bridging col.1 and col. 2 which recites:

> To examine protein activity in a format that allows the assay of every predicted ORF: we constructed an array of hybrid proteins. At least two general types of protein array may be envisioned: those composed of living transformants….. and those composed solely of the purified proteins (7). The two- hybrid array used here is a set of yeast colonies derived from about 6,000 individual transformants…..

Claims 1-11, 141, 181-186, 188, and 193-195 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shalon (WO 95/35505) in view of Felder et al (USP 6458533) or Lafferty(USP 6972183) for reasons of record as repeated below.

Shalon discloses at e.g., page 12, lines 3-9:

> A microarray as an array of regions having a density of discrete regions of at least about 100/cm2, and preferably at least about 1000/cm2. The regions in a microarray have typical dimensions, e.g., diameters, in the range of between about 10-250 um, and are separated from other regions in the array by about the same distance.

Shalon discloses at e.g., page 30, line 30 up to page 32, line 15:

> Sheets of plastic-backed nitrocellulose where each microarray could contain, for example, 100 DNA fragments representing all known mutations of a given gene. The region of interest from each of the DNA samples from 96 patients could be amplified, labeled, and hybridized to the 96 individual arrays with each assay performed in 100 microliters of hybridization solution…… In addition to the

> genetic applications listed above, arrays of… enzymes…. preparations…..

Shalon discloses an array of enzymes and not kinase as claimed. However, Feder discloses:

Feder discloses at Example 18:

> Kinases are enzymes that attach a phosphate to proteins. Many have been shown to stimulate normal and neoplastic cell growth. Hence, compounds that inhibit specific kinases (but not all kinases) can be used to test whether the kinases are involved in pathology and, if so, to serve as starting points for pharmaceutical development… Each kinase has substrates that are partially identified, as short peptides that contain a tyrosine. Some of the kinase specificities overlap so that different kinases may phosphorylate some peptides equally but others preferentially. For the five kinases, 36 peptide substrates are selected that show a spectrum of specific and overlapping specificities.

Lafferty discloses at e.g., col. 31, lines 41-49 the conventionality of an array containing subtrate-enzymes such as kinase.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use in the array of Shalon the enzyme kinase as taught by Feder. Feder teaches that kinase have been shown to stimulate normal and neoplastic cell growth. To use the kinase in the array of Shalon would lead one having ordinary skill in the art in determining the kinase in the array responsible for neoplastic

or normal cell growth. Furthermore, as taught by Lafferty an array containing a kinase is known in the art. [See also applicants' admission in the response at page 17, of the 12/19/2006 REMARKS. Applicant states: compositions ***utilizing well-known and well-characterized classes of proteins***, as in the presently claimed invention].

Response to Arguments

Applicants note that Shalon is primarily directed to arrays comprising polynucleotides (see Examples 1-3), and only mentions in passing that arrays comprising proteins and enzymes could be constructed.

In reply, in considering disclosure of a reference, it is proper to take into account not only specific teachings of the reference but also "inferences" which one skilled in the art would reasonably be expected to draw therefrom. In re Preda 159 USPQ 342. Accordingly, the mention of protein array in Shalon suffices the prima facie finding of obviousness.

Felder discloses preparation of arrays comprising peptides that are substrates for kinases, not arrays comprising the kinases themselves, "[a] chimeric linker molecule is prepared in which a 25 base pair oligonucleotide complementary to one of the anchors is

crosslinked to a peptide substrate of a tyrosine phosphokinase enzyme." Felder at column 44, lines 18-21 (emphasis added). Thus, Felder does not disclose the preparation of arrays comprising 61 purified active kinases or functional kinase domains thereof, as recited in present claim 1.

With regard to Lafferty, Applicants note that the arrays disclosed therein are limited to enzymes expressed in expression library cells, and that Lafferty does not disclose the purification of these enzymes prior to placement on a solid support, as recited in the presently claimed invention.

In response, Felder is employed not for the purpose as argued rather for its disclosure of the known kinases. Shalon teaches the arrays of enzymes, to which the specific enzyme kinase would be prima facie obvious to position therein as Felder teaches the known kinases. Lafferty is also employed not for the purpose as argued. Please see the rejection above. Hence, the combined teachings of the prior art would lead one having ordinary skill in the art to the claimed array of purified kinase.

When considering obviousness of a combination of known elements, the operative question is thus "whether the improvement is more than the predictable use of prior art

elements according to their established functions." KSR International Co. v. Teleflex Inc., 550 USPQ2d 1385 (2007).

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TERESA WESSENDORF whose telephone number is (571)272-0812. The examiner can normally be reached on flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/TERESA WESSENDORF/
Primary Examiner, Art Unit 1639